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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/364,930

07/30/1999

DANIEL T. HEINZE

10036/002001

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01/07/2002

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EXAMINER

THOMAS, JOSEPH

ART UNIT

PAPER NUMBER

2644

DATE MAILED: 01/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/364,930

Applicant(s)

HEINZE ET AL.

Examiner

Joseph Thomas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/30/1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed 30 July 1999. Claims 1-41 are pending. The IDS statements filed 16 January 2001 and 26 March 2001 have been entered and considered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. ("Natural Language Processing in an Operational Clinical Information System", *Natural Language Engineering*, vol. 1, May 1995, pp. 83-108) in view of Caid et al. (5,619,709).

- (A) As per claim 1, Friedman discloses a computerized method and system for natural language processing in an operational clinical information system, comprising:

(a) a pre-processor for preprocessing a report into different sections and separating free-form textual data from the formatted data (Friedman; pages 88 & 90-92 and fig. 2);

(b) a parser for recognizing the structure of individual sentences and generating intermediate target forms and a computational regularizer for standardizing target output forms (Friedman; pages 88 & 92-94 and fig. 2);

(c)-(d) an encoder for matching correspondences from report data to a controlled vocabulary or specific dictionary and generating structured codes therefrom (Friedman; pages 88 & 94-95); and

(e) an interface for outputting the structured encoded form (Friedman; pages 86 & 88-89).

Friedman fails to expressly disclose the use of knowledge vector processing in generating code, but does suggest that the use of automated natural language processing technology (NLP) to extract and structure clinical data (Friedman; page 96).

Moreover, the use of context vectors to represent medical procedures and their matching ICD9 codes are old and well known in the art, as evidenced by Caid.

In particular, Caid discloses a system and method of context vector generation and retrieval, wherein context vectors are generated to represent conceptual relations among information items by quantitative means (Caid; abstract; and col. 5, line 49 to col. 9, line 46), and wherein the context vectors can represent medical procedures that are matched to ICD9 codes (Caid; col. 12, lines 31-38 and col. 39, lines 51-55).

One having ordinary skill would have found it obvious to include the aforementioned features of Caid within the Friedman system with the motivation of quantitatively capturing the sensitivity of word meanings in a manner that requires less time to search and retrieve data in medical records (Caid; col. 1, line 58 to col. 3, line 24).

(B) As per claims 2-5, Friedman discloses receiving medical information related to a patient, wherein the medical data would include diagnosis/procedure information, patient-oriented clinical events and results, clinical data concepts in a Medical Entries Dictionary (MED), medical logic modules (MLMs) (Friedman; pages 85-86). Note also the teachings of Caid with respect to the use of context vectors to represent medical procedures that are matched to ICD9 codes (Caid; col. 12, lines 31-38 and col. 39, lines 51-55).

As per the recitation of extracting clinical information and demographic information, it is noted that Friedman's MEDLEE system extracts, structures, and encodes clinical information from textual patient reports (Friedman; abstract and pages 83-84), which apparently would include therein patient demographic data.

(C) As per claim 6, Friedman discloses a parser for recognizing the structure of individual sentences and generating intermediate target forms therefrom (Friedman; pages 88 & 92-94 and fig. 2). Since each radiology report would be unique to a particular individual (see fig. 4, page 91 of Friedman), it would have required no

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hindsight to associated parse items which the specific individual to which the report pertains.

(D) As per claim 7, note the discussion given above in the rejection of claim 1 with regard to Caid's disclosure of context vectors which represent medical procedures that are matched to ICD9 codes. It is respectfully submitted that once the prior art clearly establishes the use of vector analysis to recognize medical procedures and ICD9, it would have required no hindsight on the part of the skilled artisan to associate matches to more than one code. The motivation being to account for multiple procedures in a simple and efficient manner.

(E) As per claims 8-9, note the descriptions given by Caid for generating context vectors, and for analyzing the normalization of such vectors to create summary vectors (Caid; abstract; fig. 4; and col. 5, line 49 to col. 9, line 46)

(F) As per claims 10-12, Friedman is directed to a clinical information system having a plurality of databases, a Medical Entities Dictionary (MED), several Medical Logic Modules (MLMs), and Event Monitors, as sources from which data is gathered (i.e., "downloaded"), searched (via a request), and retrieved (Friedman; pages 86-87 and fig. 1). In addition, Caid is directed to searching and retrieving data based on a matching of context vectors in a query (i.e., "request") to similar context vector data contained in a collection of documents of a database (Caid; col. 11, line 5 to col. 13, line 8).

(F) Claim 13 differs from method claim 1 by reciting hardware elements, namely, a master import /export module, a filter module, and a natural language processing (NLP) engine. As per these elements, Friedman teaches:

a clinical information system which includes interface programs to import/export data from a plurality of databases or computer processors (Friedman; pages 86-87 and fig. 1);

a parser (reads on "filter module") for recognizing the structure of individual sentences and generating intermediate target forms and a computational regularizer for standardizing (i.e., "normalizing") target output forms (Friedman; pages 88 & 92-94 and fig. 2); and

MEDLEE system that extracts, structures, and encodes clinical information from textual patient reports via automated natural language processing technology (NLP) (Friedman; abstract, and pages 83-84 & 96).

The remainder of system claim 13 repeats the same limitations of method claim 1, and is therefore rejected for the same reasons given above for claim 1, and incorporated herein.

(G) Claims 14-23 & 25 repeat the same limitations of claims 2-12, and are therefore rejected for the same reasons given for those claims.

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(H) As per claims 24, 30, and 32, Friedman discloses the use of different levels of evaluations manually reviewed by human operators to determine the degree of performance of the MEDLEE system (see pages 97-105). Since the evaluations require quantitative and qualitative analysis of the automated extraction and processing results, it is readily apparent that such evaluation were performed or coordinated in some type of review workstation. As per the recitation of templates, it is noted that Friedman's pre-processor segments a report into different sections and separates free-form textual data from the formatted data (Friedman; pages 88 & 90-92 and fig. 2) and the parser generates intermediate target forms (Friedman; pages 88 & 92-94 and fig. 2). Intermediate target forms are considered to a form of template.

(I) As per claim 26, note the teachings of Caid with respect to a system and method of context vector generation and retrieval, wherein context vectors are generated to represent conceptual relations among information items by quantitative means (Caid; abstract; and col. 5, line 49 to col. 9, line 46), and wherein the context vectors can represent medical procedures that are matched to ICD9 codes (Caid; col. 12, lines 31-38 and col. 39, lines 51-55).

(J) As per claims 27-28, Friedman and Caid fail to expressly disclose a payer process module and a client billing system, per se. However, Friedman's clinical information system includes a database interface to administrative module (see pages 86-87 and fig. 1 of Friedman). It is respectfully submitted that the processing of payer

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data and client billing is a critical administrative function, and the skilled artisan would have found it an obvious modification to have included the processing of payer data and client billing within the system taught collectively by Friedman and Caid with the motivation of ensuring proper authorization and compensation for health care services rendered.

(K) As per claim 29, note page 95 of Friedman with respect to weighting coded values to concepts associated with degree such as low degree, moderate degree, high degree, etc.

The skilled artisan motivated to combine the respective teachings of Friedman and Caid for the same reasons given above in the rejection of claim 1 would likewise have found to obvious to weight context vectors in a similar fashion, so as to properly match encoded data with context vector data.

(L) As per claim 31, Friedman's clinical information system includes a database interface to a number of system elements, including a plurality of databases, a Medical Entities Dictionary (MED), several Medical Logic Modules (MLMs), Event Monitors, and an administrative module (see pages 86-87 and fig. 1 of Friedman). As such, it is readily apparent that Friedman's database interface would have included a input device such as mouse or keyboard and a display. In addition, note col. 4, line 45 to col. 5, line 14 of Caid with respect to the use of input devices and display devices.

Insofar as Applicant recites the phrase "one of" within claim 31, it is irrelevant whether or not the applied references disclose an optical character recognizer, or an automatic speech recognition device.

(M) Claim 33 differs from method claim 1 by reciting "a computer program, stored in a computer-readable medium" and "the computer program comprising instructions" within its preamble. As per these elements, Friedman clinical information system includes a database interface to a number of system elements, including a plurality of databases and computer processing devices such as a Medical Entities Dictionary (MED), several Medical Logic Modules (MLMs), Event Monitors, and an administrative module (see pages 86-87 and fig. 1 of Friedman). As such, it is readily apparent that Friedman's clinical information system is controlled by a computer program stored upon a computer-readable medium. . In addition, note col. 4, line 45 to col. 5, line 14 of Caid.

The remainder of system claim 33 repeats the same limitations of method claim 1, and is therefore rejected for the same reasons given above for claim 1, and incorporated herein.

(N) Claims 34-41 repeat the same limitations of claims 2-9, and are therefore rejected for the same reasons given for those claims.

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Conclusion

4. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied prior art teaches a computerized medical diagnostic system including re-enter function and sensitivity codes (5,594,638); a system and methods for word recognition (5,680,511); and visualization of information using graphical representations of context vector based relationships and attributes (5,794,178).

5. **Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703)872-9314

For informal or draft communications, please label "PROPOSED" or "DRAFT" on the front page of the communication, and do NOT sign the communication.

Hand-delivered responses should be brought to Crystal Park II,
2121 Crystal Drive, Arlington, VA, Sixth Floor (Receptionist).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Thomas, whose telephone number is (703) 305-9588. The examiner can normally be reached on Monday through Thursday from 9:30 AM to 7:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiners' supervisor, Forester W. Isen, can be reached at (703) 305-4386.

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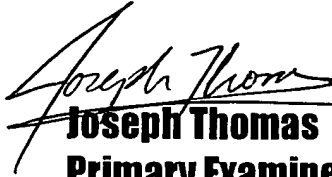
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Any inquiry of a general nature or relating to the status of this application should be directed to the Group Customer Service Department whose telephone number is (703) 306-0377.

jt

December 17, 2001


Joseph Thomas
Primary Examiner
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